

AMENDMENTS TO THE CLAIMS

This listing of the claims replaces all prior versions, and listings of the claims in the application:

1. (Original) An auto-titration pressure support system comprising:

a pressure generating system adapted to generate a flow of breathing gas at a selectable pressure level and to change the pressure level from a base pressure during a respiratory cycle;

a patient circuit having a first end adapted to be coupled to the pressure generating system and a second end adapted to be coupled to an airway of a patient;

a monitoring system associated with the patient circuit or the pressure generating system and adapted to measure a parameter indicative of a pressure at a patient's airway, a flow of gas in such a patient's airway, or both and to output a pressure signal, a flow signal indicative thereof, respectively, or both; and

a controller coupled to the monitoring system and the pressure generating system, for controlling the base pressure of the pressure generating system based on the output of the monitoring system, wherein the controller is programmed to operate according to one control layer in a set of prioritized control layers, wherein each control layer in the set of prioritized control layers competes for control of the pressure generating system with the other control layers, and wherein each control layer implements a unique pressure control process for controlling the pressure of the flow of breathing gas output by the pressure generating system.

2. (Original) The system of claim 1, wherein each control layer in the set of prioritized control layer includes:

a detection module that receives the pressure signal, the flow signal, or both;

a monitoring module that monitors an output of the detection module to determine whether to request that the control layer take control of the pressure generating system; and

a control module that controls the operation of the pressure generating system responsive to the control layer being granted control thereof.

3. (Original) The system of claim 1, wherein the set of prioritized control layers include:

(a) flow limit control layer that monitors the flow signal to determine whether the pressure generating system is exhibiting a large leak indicative of the patient circuit not being connected to an airway of a patient, and causes the pressure generating system to lower the pressure of the flow of breathing gas responsive to detection of the large leak and maintains the pressure generating system at the lower pressure;

(b) snore control layer that monitors the flow signal, the pressure signal, or both for snoring, and causes the pressure generating system to increase the pressure of the flow of breathing gas responsive to detection of snore;

(c) a big leak control layer that monitors the flow signal to determine whether the pressure generating system is exhibiting a leak that is less than the large leak but great enough to cause the pressure support system to not operate reliably, and causes the pressure generating system to lower the pressure of the flow of breathing gas responsive to detection of the large leak for predetermined period of time;

(d) an apnea/hypopnea control layer that monitors the flow signal, the pressure signal, or both to determine whether the patient is experiencing an apnea, a hypopnea, or both, and causes the pressure generating system to adjust the pressure of the flow of breathing gas responsive to detection of apnea, hypopnea, or both;

(e) a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing, and causes the pressure generating system to adjust the pressure of the flow of breathing gas responsive to detection of erratic breathing;
and

(f) an auto-CPAP control layer that controls the pressure of the flow of breathing gas responsive to proactively search for a pressure that optimizes the pressure provided to the patient to treat disordered breathing.

4. (Original) The system of claim 3, wherein:

(1) the flow limit control layer has a higher priority than the snore control layer, the big leak control layer, the apnea/hypopnea control layer, the variable breathing control layer, and the auto-CPAP control layer;

(2) the snore control layer has a higher priority than the big leak control layer, the apnea/hypopnea control layer, the variable breathing control layer, and the auto-CPAP control layer and has a lower priority than the flow limit control layer;

(3) the big leak control layer has a higher priority than the apnea/hypopnea control layer, the variable breathing control layer, and the auto-CPAP control layer and has a lower priority than the flow limit control layer and the snore control layer;

(4) the apnea/hypopnea control layer has a higher priority than the variable breathing control layer, and the auto-CPAP control layer and has a lower priority than the flow limit control layer, the snore control layer, and the big leak control layer; and

(5) the variable breathing control layer has a higher priority than the auto-CPAP control layer and has a lower priority than the flow limit control layer, the snore control layer, the big leak control layer, and the apnea/hypopnea control layer.

5. (Original) The system of claim 1, further comprising a manual input for controlling the operation of the pressure support system, and wherein the set of prioritized control layers include at least one first control layer that is initiated based on the manual input and at least one second control layer that is initiated based on the pressure signal, the flow signal or both, wherein the at least one first control layer has a higher priority than the at least one second control layer.

6. (Original) The system of claim 5, wherein the first control layer is a ramp control layer that causes the pressure generating system to gradually increase the pressure of the flow of breathing gas from a relatively low level to a target level responsive to receipt of a ramp activation signal as the manual input.

7. (Original) The system of claim 6, wherein the second control layer includes at least one of the following control layers:

(a) flow limit control layer that monitors the flow signal to determine whether the pressure generating system is exhibiting a large leak indicative of the patient circuit not being connected to an airway of a patient, and causes the pressure generating system to lower the pressure of the flow of breathing gas responsive to detection of the large leak and maintains the pressure generating system at the lower pressure;

(b) snore control layer that monitors the flow signal, the pressure signal, or both for snoring, and causes the pressure generating system to increase the pressure of the flow of breathing gas responsive to detection of snore;

(c) a big leak control layer that monitors the flow signal to determine whether the pressure generating system is exhibiting a leak that is less than the large leak but great enough to cause the pressure support system to not operate reliably, and causes the pressure generating system to lower the pressure of the flow of breathing gas responsive to detection of the large leak for predetermined period of time;

(d) an apnea/hypopnea control layer that monitors the flow signal, the pressure signal, or both to determine whether the patient is experiencing an apnea, a hypopnea, or both, and causes the pressure generating system to adjust the pressure of the flow of breathing gas responsive to detection of apnea, hypopnea, or both;

(e) a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing, and causes the pressure generating system to adjust the pressure of the flow of breathing gas responsive to detection of erratic breathing; and

(f) an auto-CPAP control layer that controls the pressure of the flow of breathing gas responsive to actively search for a pressure that optimizes the pressure provided to the patient to treat disordered breathing.

8. (Withdrawn) A method of providing pressure support to a patient, comprising: providing flow of breathing gas at a selectable pressure level to an airway of a patient;

changing the pressure level from a base pressure during a respiratory cycle;

monitoring a pressure, a flow, or both of the flow of breathing gas and outputting a pressure signal, a flow signal indicative thereof, respectively, or both;

selecting a control layer from a set of prioritized control layers based on the pressure signal, the flow signal, or both; and

controlling the base pressure according to a pressure control technique unique to the selected pressure control layer.

9. (Withdrawn) The method of claim 8, wherein the set of prioritized control layers include:

(a) flow limit control layer that monitors the flow signal to determine whether the pressure generating system is exhibiting a large leak indicative of the patient circuit not being connected to an airway of a patient, and causes the pressure generating system to lower the pressure of the flow of breathing gas responsive to detection of the large leak and maintains the pressure generating system at the lower pressure;

(b) snore control layer that monitors the flow signal, the pressure signal, or both for snoring, and causes the pressure generating system to increase the pressure of the flow of breathing gas responsive to detection of snore;

(c) a big leak control layer that monitors the flow signal to determine whether the pressure generating system is exhibiting a leak that is less than the large leak but great enough to cause the pressure support system to not operate reliably, and causes the pressure generating

system to lower the pressure of the flow of breathing gas responsive to detection of the large leak for predetermined period of time;

(d) an apnea/hypopnea control layer that monitors the flow signal, the pressure signal, or both to determine whether the patient is experiencing an apnea, a hypopnea, or both, and causes the pressure generating system to adjust the pressure of the flow of breathing gas responsive to detection of apnea, hypopnea, or both;

(e) a variable breathing control layer that monitors the flow signal to determine whether the patient is experiencing erratic breathing, and causes the pressure generating system to adjust the pressure of the flow of breathing gas responsive to detection of erratic breathing; and

(f) an auto-CPAP control layer that controls the pressure of the flow of breathing gas responsive to actively search for a pressure that optimizes the pressure provided to the patient to treat disordered breathing.

10. (Withdrawn) The method of claim 9, wherein selecting a control layer includes:

(1) selecting the flow limit control layer over the snore control layer, the big leak control layer, the apnea/hypopnea control layer, the variable breathing control layer, and the auto-CPAP control layer;

(2) selecting the snore control layer over the big leak control layer, the apnea/hypopnea control layer, the variable breathing control layer, and the auto-CPAP control layer but not over the flow limit control layer;

(3) selecting the big leak control layer over the apnea/hypopnea control layer, the variable breathing control layer, and the auto-CPAP control layer but not over the flow limit control layer and the snore control layer;

(4) selecting the apnea/hypopnea control layer over the variable breathing control layer and the auto-CPAP control layer but not over the flow limit control layer, the snore control layer, and the big leak control layer; and

(5) selecting the variable breathing control layer over the auto-CPAP control layer but not over the flow limit control layer, the snore control layer, the big leak control layer, and the apnea/hypopnea control layer.

11. (Withdrawn) The method of claim 8, further comprising receiving a manual input for controlling the operation of the pressure support system, wherein the set of prioritized control layers include at least one first control layer that is initiated based on the manual input and at least one second control layer that is initiated based on the pressure signal, the flow signal, or both, wherein the selecting step includes selecting the at least one first control layer over the at least one second control layer.

Claims 12-14. (Cancelled).

15. (Withdrawn) A method of providing pressure support to a patient, comprising:
providing flow of breathing gas at a selectable pressure level to an airway of a patient;
changing the pressure level from a base pressure during a respiratory cycle;
monitoring a flow of the flow of breathing gas and outputting a flow signal indicative thereof;
performing a trend analysis on data determined from the flow signal; and
controlling the base pressure based on the trend analysis.

16. (Withdrawn) The method of claim 15, wherein performing a trend analysis includes:
determining a plurality of values for a monitored breath parameter over a period of time;

performing a long-term trend analysis on the plurality of values for the monitored breath parameter; and

performing a short-term trend analysis on the plurality of values for the monitored breath parameter.

17. (Withdrawn) The method of claim 16, wherein performing the trend analysis further includes:

determining a trend analysis vote associated with each monitored breath parameter based on a result of the long-term trend analysis and a short-term trend analysis;

accumulating the trend analysis votes for a plurality of monitored breath parameters to determine a final vote value, and wherein the pressure is controlled in the pressure controlling step based on the final vote value.

Claims 18 and 19. (Cancelled).

20. (Withdrawn) A method of providing pressure support to a patient, comprising:

providing flow of breathing gas at a selectable pressure level to an airway of a patient;

changing the pressure level from a base pressure during a respiratory cycle;
monitoring a flow of the flow of breathing gas and outputting a flow signal indicative thereof;

determining a breathing parameter from the flow signal;

analyzing a variability of the breathing parameter; and

controlling the pressure based on a result of the variability analysis.

21. (Withdrawn) The method of claim 20, wherein analyzing the variability of the breathing parameter includes:

calculating a weighted peak flow and a best-fit trend line for the weighted peak flow over a plurality of breathing cycles; and

calculating a variable breathing number (VB#) as follows:

$$VB\# = \frac{\text{standard deviation}}{\text{adjusted mean flow}},$$

wherein the standard deviation is calculated as a standard deviation of the weighted peak flows over a plurality of breathing cycles from the best-fit trend line, and wherein the adjusted mean flow is determined based on an actual patient flow determined from the flow signal.

22. (Original) An auto-titration pressure support system comprising:

a pressure generating system adapted to generate a flow of breathing gas at a selectable pressure level and to change the pressure level from a base pressure during a respiratory cycle;

a patient circuit having a first end adapted to be coupled to the pressure generating system and a second end adapted to be coupled to an airway of a patient;

a monitoring system associated with the patient circuit or the pressure generating system and adapted to measure a parameter indicative of a flow of gas in such a patient's airway and to output a flow signal indicative thereof; and

a controller coupled to the monitoring system and the pressure generating system, for controlling the base pressure based on the output of the monitoring system, wherein the controller determines a skewness of a patient's inspiratory waveforms from the output of the flow sensor and controls the pressure generating system according to the skewness determination.

23. (Original) The system of claim 22, wherein the controller determines the skewness of the inspiratory waveform by segmenting the inspiratory waveform into a first region that corresponds to a beginning portion of the inspiratory waveform and a second region that

corresponds to a middle portion of the inspiratory waveform, and comparing the flow in the second region to the flow in the first region.

24. (Original) The system of claim 23, wherein the flow in the first region corresponds to an average of the highest rates of flow in the first region, and wherein the flow in the second region corresponds to an average of the highest rates of flow in the second region.

25. (Original) The system of claim 23, wherein the first region corresponds to approximately a first third of the inspiratory waveform and the second region corresponds to approximately a second third of the inspiratory waveform, and wherein the highest flow rates in the first region and the second region are defined as the flow rates within 5% of the highest flow rates in each region.

26. (Original) The system of claim 23, wherein the skewness is calculated as a skewness number follows:

$$\text{skewness number} = \frac{\text{Average of the highest flow rates in the second region}}{\text{Average of the highest flow rates in the first region}}.$$

27. (Withdrawn) A method of providing pressure support to a patient, comprising:
providing a flow of breathing gas at a selectable pressure level to an airway of a patient;
changing the pressure level from a base pressure during a respiratory cycle;
monitoring a flow of the flow of breathing gas and outputting a flow signal indicative thereof;
determining a skewness of a patient's inspiratory waveforms from the flow signal;
and
controlling the base pressure based on the skewness determination.

28. (Withdrawn) The method of claim 27, wherein determining the skewness of the inspiratory waveform includes:

segmenting the inspiratory waveform into a first region that corresponds to a beginning portion of the inspiratory waveform and a second region that corresponds to a middle portion of the inspiratory waveform; and

comparing the flow in the second region to the flow in the first region.

29. (Withdrawn) The method of claim 28, further comprising determining an average of the highest rates of flow in the first region, and determining an average of the highest rates of flow in the second region, and wherein the comparing step includes comparing the average of the highest rates of flow in the first region with the average of the highest rates of flow in the second region.

30. (Withdrawn) The method of claim 28, wherein the first region corresponds to approximately a first third of the inspiratory waveform and the second region corresponds to approximately a second third of the inspiratory waveform, and wherein the highest flow rates in the first region and the second region are defined as the flow rates within 5% of the highest flow rates in each region.

31. (Withdrawn) The method of claim 28, wherein the comparing step includes determining the skewness as a skewness number as follows:

$$\text{skewness number} = \frac{\text{Average of the highest flow rates in the second region}}{\text{Average of the highest flow rates in the first region}}.$$

32. (Original) An auto-titration pressure support system comprising:

a pressure generating system adapted to generate a flow of breathing gas at a selectable pressure level and to change the pressure level from a base pressure during a respiratory cycle;

a patient circuit having a first end adapted to be coupled to the pressure generating system and a second end adapted to be coupled to an airway of a patient;

a monitoring system associated with the patient circuit or the pressure generating system and adapted to measure a parameter indicative of a pressure at a patient's airway, a flow of gas in such a patient's airway, or both and to output a pressure signal, a flow signal indicative thereof, respectively, or both; and

a controller coupled to the monitoring system and the pressure generating system, for controlling the pressure generating system based on the output of the monitoring system, wherein the controller is programmed to:

- (1) determine whether the patient is experiencing an apnea/hypopnea based on the pressure signal or the flow signal,
- (2) set a pressure treatment limit based on a pressure at a time an apnea/hypopnea is detected,
- (3) cause the pressure generating system to increase the base pressure responsive to a current pressure being below the pressure treatment limit, and
- (4) cause the pressure generating system to decrease the base pressure responsive to a current pressure being at or above the pressure treatment limit.

33. (Withdrawn) A method of providing pressure support to a patient, comprising:

providing flow of breathing gas at a selectable pressure level to an airway of a patient;

changing the pressure level from a base pressure during a respiratory cycle;

monitoring a pressure, a flow, or both of the flow of breathing gas and outputting a pressure signal, a flow signal indicative thereof, respectively, or both;

determine whether the patient is experiencing an apnea/hypopnea based on the pressure signal, the flow signal, or both;

setting a pressure treatment limit based on a pressure at a time an apnea/hypopnea is detected;

increasing the base pressure responsive to a current pressure being below the pressure treatment limit; and

decreasing the base pressure responsive to a current pressure being at or above the pressure treatment limit.

34. (New) An auto-titration pressure support system comprising:

a pressure generating system adapted to generate a flow of breathing gas at a selectable pressure level and to change the pressure level from a base pressure during a respiratory cycle;

a patient circuit having a first end adapted to be coupled to the pressure generating system and a second end adapted to be coupled to an airway of a patient;

a monitoring system associated with the patient circuit or the pressure generating system and adapted to measure a parameter indicative of a flow of gas in such a patient's airway and to output a flow signal indicative thereof; and

a controller coupled to the monitoring system and the pressure generating system, for controlling the pressure generating system based on the output of the monitoring system, wherein the controller is programmed determine whether the patient is experiencing a central apnea/hypopnea or an obstructive/restrictive apnea/hypopnea by monitoring one or more of the following: (1) at least one shape parameter associated with the flow of gas during an apnea/hypopnea period, and (2) a characteristic of the flow of gas at the end of the apnea/hypopnea period indicative of an increase in respiratory effort, wherein the shape parameters monitored by the controller during an apnea/hypopnea period includes a flatness of an inspiratory portion of a flow waveform, a roundness of the inspiratory portion of the flow waveform, a skewness of the inspiratory portion of the flow waveform, and wherein the

controller considers a patient to be experiencing an obstructive/restrictive apnea/hypopnea responsive to the inspiratory portion of the flow waveform exhibiting at least one of an increase in flatness, a decrease in roundness, and an increased skewness, otherwise the controller considers the patient to be experiencing a central apnea/hypopnea, and wherein the controller prevents a pressure increase by the pressure generating system responsive to a determination that the patient is experiencing a central apnea/hypopnea.